Appln. No.: 10/081,641

Amendment Dated November 17, 2005

Reply to Office Action of September 29, 2005

## **Remarks:**

The Office Action of September 29, 2005 ("the Office Action") rejected pending claims 1, 3-8, 10, 11, 17, 30-33, 47, and 51. Claims 1, 3-8, 10, 11, 17, 30, 32, 47 and 51 stand rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 5,201,757 to Heyn et al. (Heyn) in view of U.S. Patent No. 6,042,589 to Marianne (Marianne). The Office Action also rejected pending claims 31 and 33 under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 5,201,757 to Heyn in view of U.S. Patent No. 5,445,646 to Euteneuer (Euteneuer).

Heyn teaches a device configured to deploy a prosthesis starting from its medial region. See, e.g., Heyn Fig. 5b. The deployment device taught by Heyn also includes an anchoring means in the form of one or more detents identified in various embodiments as 54, 102, and 104. However, these detent/anchoring means taught by Heyn differ from the anchoring means disclosed and claimed by Applicants. The detents taught by Heyn fix the unexpanded stent portion inside the introducer against the inner surface of its sheath. See, e.g., Heyn Fig. 4.

In contrast, Applicants' pending claim 1, as amended, properly invokes means-plus-function language permissible under § 112 ¶6 to claim structures that provide one or more "anchoring means" that fix an *expanded* stent portion *outside* the introducer *against the body lumen*. The detents disclosed by Heyn and cited in the Office Action are incapable of performing in this manner because they cannot exert a radial force and because they remain, at all times, confined within Heyn's deployment device. Thus, to address the problem of stent movement during deployment, Heyn teaches *only* structures to fix a stent within the introducer. Heyn neither teaches nor suggests the fixation of a stent against a body lumen for anchoring.

Marianne teaches a traditional, distal-end first, deployment device equipped with a "micro-balloon" 20 whose principal use is, by its slight inflation, "causing the primal end of the stent 7 to be firmly locked in place with respect to the inner tube 8" of the device. See Marianne, column 3, lines 5-9. Like Heyn, this deployment use taught by Marianne also fixes the unexpanded stent portion inside the deployment device and against the inner surface of its inner tube. See Marianne Fig. 2. Marianne also discloses secondary uses for its micro-balloon whereby (1) its additional friction is used hold the stent in place relative to the deployment device while dragging the entire apparatus in a proximal direction should some error occur during initial placement of the stent (column 3, lines 28-34) or (2) as a traditional dilatation balloon to expand the stent fully against resistance posed by a stenosis (column 3, lines 45-53). Marianne does not teach or suggest the use of its balloon as an "anchoring means" to fix an expanded stent portion outside the deployment device against the body lumen during unsheathing of a remaining portion of the endoluminal device distal of the proximal end, nor could it be used in such a manner.

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Applicants respectfully submit that the Office Action has advanced no need, and hence no suggestion, for either reference to adopt or be combined with the structure disclosed in the other reference to arrive at Applicants' invention as claimed. Specifically, there is no suggestion to combine features of a medial-region-first stent deployment device having an internal anchoring means as taught by Heyn with a deployment device having a balloon as taught by Marianne for either fixing its stent within the device or expansion against a stenosis. Heyn resolves its stent-positioning problems by fixing its stent within its deployment device. Marianne likewise resolves its stent positioning problems by fixing its stent within its deployment device. One skilled in the art would not be motivated to selectively combine the two references to address a problem that each reference purports to solve. This is particularly true where Applicants' claimed means for anchoring one end of the stent while the remaining portion of the stent is deployed is inconsistent with the stated object of Heyn to "provide an apparatus for deploying a radially self-expanding stent, initially only along a medial region of the stent while the axially outward end regions of the stent remain confined in a reduced radius configuration," thereby teaching away from a construction such as claimed by Applicants. Column 2, lines 1-5. Thus, even if the two references could be cobbled together to form Applicants' invention, the sole motivation for the proposed combination would be Applicants' own disclosure, which is impermissible hindsight.

In *Ex parte Metcalf*, 67 USPQ2d 1633 (2003), the Board of Patent Appeals and Interferences cited caselaw to stress that there must be objective motivation to support an obviousness rejection. More specifically, the mere fact that teachings found in the prior art could be combined as proposed by an examiner does not make the combination obvious "absent some teaching, suggestion or incentive supporting the combination." *Id.* at 1635 (citing *Carella v. Starlight Archery and Pro Line Co.*, 231 U.S.P.Q. 644, 647 (Fed. Cir. 1986)). It is respectfully submitted that the Office Action has failed to identify any such teaching, suggestion, or incentive to support the proposed combination. Accordingly, it is respectfully submitted that independent claims 1 and 47, as amended, are patentable over the art of record. Likewise, it is respectfully submitted that the remaining dependent claims, which depend, directly or indirectly from claims 1 and 47, are also patentable over the art of record.

Further, Euteneuer does not teach or suggest, singly or in combination with Heyn, the limitations of independent claim 1. Therefore, because claims 31 and 33 depend from and incorporate the limitations of patentable, independent claim 1 and their respective intervening claims, claims 31 and 33 are distinguishable from the cited art for at least this reason.

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## **Conclusion:**

In view of the remarks above, Applicants contend that the above-identified application is in condition for allowance, which action is respectfully requested. As a number of withdrawn claims are also dependent from allowable claims, Applicants further request allowance of such withdrawn claims as well.

Respectfully submitted

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